

# Short versus standard treatment with pegylated interferon alfa-2a plus ribavirin in patients with hepatitis C virus genotype 2 or 3: the CLEO trial

<b>Submission date</b> 15/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
22/2006

## Study information

**Scientific Title**  
Short versus standard treatment with pegylated interferon alfa-2a plus ribavirin in patients with hepatitis C virus genotype 2 or 3: a randomised controlled trial

**Acronym**

Study short treatment (reduction duration)

**Study objectives**

To verify if a 12-week regimen of a combination of pegylated interferon alfa-2a and ribavirin was as efficacious as a 24-week regimen in patients with hepatitis C virus (HCV) genotype 2 or 3.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethical Committee of Azienda Ospedaliera San Camillo Forlanini approved in 2005 (ref: 489)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Chronic hepatitis C genotype 2 and 3

**Interventions**

Patients fulfilling the selection criteria received in an open-label fashion pegylated interferon alfa-2a at a dose of 180 µg subcutaneously once weekly and oral ribavirin, at a dosage of 1000 mg/day (for those with a weight of less than 75 kg) or 1200 mg/day (for those with a weight of greater than or equal to 75 kg). Patients with rapid virological response (RVR) defined as HCVRNA less than 50 IU/ml after 4 weeks of treatment, were randomly assigned in a 1:1 ratio to receive a treatment either for 12 weeks. Patients without RVR were treated for a standard period of 24 weeks.

**Intervention Type**

Drug

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Pegylated interferon alfa-2a, ribavirin

**Primary outcome(s)**

Sustained virological response (SVR) which was defined as undetectable plasma HCVRNA (less than 50 IU/ml) 24 weeks after the end of treatment.

**Key secondary outcome(s)**

1. Virological response rates (HCV RNA negative in serum with a detection limit of 50 IU/ml) at the end of therapy
2. Severity and frequency of adverse events

**Completion date**

10/01/2008

## Eligibility

**Key inclusion criteria**

1. HCV ribonucleic acid (RNA) positive
2. HCV genotype 2 or 3
3. Elevated alanine aminotransferase (greater than 40 IU/L) at least 8 months prior to study entry
4. Histologically proven chronic HCV hepatitis
5. Naive to treatment
6. Aged 20 - 68 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

210

**Key exclusion criteria**

1. Known to have injected drugs or alcohol abuse (greater than 40 g ethanol/day) within the 6 months prior to study entry
2. Poorly controlled psychiatric illness
3. Decompensated cirrhosis
4. Positive for human immunodeficiency antibody virus or positive for hepatitis B surface antigen
5. Pregnancy, lactation
6. Impaired renal function
7. Other concurrent medical conditions of the liver different from HCV infection

**Date of first enrolment**

10/05/2006

**Date of final enrolment**

10/01/2008

## Locations

## Countries of recruitment

Italy

## Study participating centre

Via Terni 97 (private address)

Rome

Italy

00182

# Sponsor information

## Organisation

Club Hepatology Hospital (Club Epatologi Ospedalieri [CLEO]) Group (Italy)

# Funder(s)

## Funder type

Research organisation

## Funder Name

Club Hepatology Hospital (Club Epatologi Ospedalieri [CLEO]) Group (Italy)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	19/02/2010	29/12/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes